K072918

510(k) Summary of Safety and Effectiveness: 21 CFR 807.92

Submitter's Name: Toshiba America Medical Systems, Inc.
Address: PO Box 2068, 2441 Michelle Drive Tustin, CA 92781-2068
Contact: Paul Biggins, Director Regulatory Affairs
Telephone No.: (714) 730-5000

Device Proprietary Name: SSA-680A, Xario XG Version 1.00
Common Name: Diagnostic Ultrasound System

Classification:
Regulatory Class: II
Review Category: Tier II

- Ultrasonic Pulsed Doppler Imaging System – Product Code: 90-IYN [Fed. Reg. No.: 892.1550]
- Ultrasonic Pulsed Echo Imaging System – Product Code: 90-IYO [Fed. Reg. No.: 892.1560]
- Diagnostic Ultrasonic Transducer – Product Code: 90-ITX [Fed. Reg. No.: 892.1570]

Identification of Predicate Devices:
Toshiba America Medical Systems believes that this device is substantially equivalent to:

Toshiba SSA-790A, Aplio XG Version 2.00 Diagnostic Ultrasound; 510(k) K072000

Device Description:
The Xario XG Ultrasound System is a mobile system. This system is a Track 3 device that employs a wide array of probes including, flat linear array, convex linear array, and sector array with a frequency range of approximately 2 MHz to 12 MHz.

Intended Use:
The Xario XG is intended to be used for the following type of studies; fetal, abdominal, intraoperative, pediatric, small organs, neonatal cephalic, adult cephalic, cardiac, transrectal, transvaginal, transesophageal, peripheral vascular and musculo-skeletal (both conventional and superficial).

Safety Considerations:
This device is designed and manufactured in conjunction with the Quality System Regulation, IEC 60601-1 (applicable portions), IEC 60601-1-2 (applicable portion), IEC60601-2-37 (applicable portions), and the AIUM-NEMA UD2 Output Measurement Standard as applied to Track 3 Ultrasound systems and the AIUM-NEMA UD3 Output Display Standard.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Toshiba America Medical System, Inc.
% Mr. Mark Job
Responsible Third Party Official
Regulatory Technology Services LLC
1394 25th Street NW
BUFFALO MN 55313

Re: K072918
Trade/Device Name: Xario XG SSA-680A Version 1.0
Regulation Number: 21 CFR 892.1560
Regulation Name: Ultrasonic pulsed echo imaging system
Regulatory Class: II
Product Code: IYO, IYN, and ITX
Dated: October 11, 2007
Received: October 15, 2007

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

This determination of substantial equivalence applies to the following transducers intended for use with the Xario XG SSA-680A Version 1.0, as described in your premarket notification:

Transducer Model Number

PVT-375BT
PVT-661VT
PLT-1202S
PC-20M
PET-510MB
PST-25BT
PVT-575MV

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This determination of substantial equivalence is granted on the condition that prior to shipping the first device, you submit a postclearance special report. This report should contain complete information, including acoustic output measurements based on production line devices, requested in Appendix G, (enclosed) of the Center's September 30, 1997 "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers." If the special report is incomplete or contains unacceptable values (e.g., acoustic output greater than approved levels), then the 510(k) clearance may not apply to the production units which as a result may be considered adulterated or misbranded.

The special report should reference the manufacturer's 510(k) number. It should be clearly and prominently marked "ADD-TO-FILE" and should be submitted in duplicate to:

Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center (HFZ-401)
9200 Corporate Boulevard
Rockville, Maryland 20850

This letter will allow you to begin marketing your device as described in your premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus permits your device to proceed to market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html

If you have any questions regarding the content of this letter, please contact Lauren Hefner at (240) 276-3666.

Sincerely yours,

for Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure(s)

Diagnostic Ultrasound Indications For Use Form

System _X__ Transducer___
Model_Xario XG SSA-680A Version 1.0
510(k) Number(s)

	Mode of Operation											
Clinical Application	B	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal	N	N	N	N	N	N		N				N
Abdominal	N	N	N	N	N	N		N	N			N
Intraoperative (Specify)	N	N	N	N	N			N				N
Intraoperative Neurological												
Pediatric	N	N	N	N	N	N	N	N	N			N
Small Organ (Specify)*	N	N	N	N	N			N				N
Neonatal Cephalic	N	N	N	N	N	N		N	N			N
Adult Cephalic	N	N	N	N	N	N		N	N			N
Cardiac	N	N	N	N	N	N	N	N	N	N		N
Transesophageal	N	N	N	N			N	N	N			N
Transrectal	N	N	N	N	N	N		N				N
Transvaginal	N	N	N	N	N	N		N				N
Transurethral												
Intravascular												
Peripheral Vascular	N	N	N	N	N			N	N			N
Laparoscopic												
Musculo-skeletal Superficial	N	N	N	N	N			N				N
Musculo-skeletal Conventional	N	N	N	N	N			N				N

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

* : For example: thyroid, parathyroid, breast, scrotum and penis

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)11

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K073918

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer _X_
Model__PVT-375BT_____
510(k) Number(s)
_____

Clinical Application	Mode of Operation											
	B	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal	P	P	P	P	P	P		P				P
Abdominal	P	P	P	P	P	P		P				P
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P		P				P
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previously Cleared 510(k): K072000

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Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072918

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PVT-661VT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal	P	P	P	P	P	P		P				P
Transvaginal	P	P	P	P	P	P		P				P
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previously Cleared 510(k): K072000

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072918

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PLT-1202S
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)	P	P	P	P	P			P				P
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*	P	P	P	P	P			P				P
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular	P	P	P	P	P			P				P
Laparoscopic												
Musculo-skeletal Superficial	P	P	P	P	P			P				P
Musculo-skeletal Conventional	P	P	P	P	P			P				P

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

Previously Cleared 510(k): K072000

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072918

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PC-20M
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric									P			
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic												
Cardiac									P			
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular									P			
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

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Additional Comments: ___

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Prescription Use (Per 21 CFR 801.109)

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Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072918

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PET-510MB
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal	P	P	P	P			P	P	P			P
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD;

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072918

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PST-25BT
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal												
Abdominal	P	P	P	P	P	P	P	P	P			P
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric	P	P	P	P	P	P	P	P	P			P
Small Organ (Specify)*												
Neonatal Cephalic	P	P	P	P	P	P		P	P			P
Adult Cephalic	P	P	P	P	P	P		P	P			P
Cardiac	P	P	P	P	P	P	P	P	P	P		P
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

N= new indication; P = Previously Cleared by FDA; E = Added under Appendix E (LTF)

Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD;B-TDI; M-TDI; 2D/CWD; BDF/CWD; CHI/2D; FEI/2D; CHI/BDF; FEI/BDF

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Prescription Use (Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K072918

Diagnostic Ultrasound Indications For Use Form

System ___ Transducer X
Model PVT-575MV
510(k) Number(s)

Clinical Application	Mode of Operation											
	B	THI	M	Color Doppler	Power	Dynamic Flow	TDI	PW	CW	CHI 2D	CHI Dynamic Flow	Combined (Specify)
Ophthalmic												
Fetal	P	P	P	P	P	P		P				P
Abdominal												
Intraoperative (Specify)												
Intraoperative Neurological												
Pediatric												
Small Organ (Specify)*												
Neonatal Cephalic												
Adult Cephalic												
Cardiac												
Transesophageal												
Transrectal												
Transvaginal												
Transurethral												
Intravascular												
Peripheral Vascular												
Laparoscopic												
Musculo-skeletal Superficial												
Musculo-skeletal Conventional												

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Additional Comments: Combined Modes: B/M; B/PWD; BDF/PWD; BDF/MDF; BDF/MDF/PWD

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